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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,935	08/17/2000	Michael S. Kinch	3220-66874	3254

26813 7590 05/23/2003

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MINNEAPOLIS, MN 55458

EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/23/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/640,935

Applicant(s)

KINCH ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 58-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of amendment, Dr. Kinch's declaration, and hydridoma availability statement, request for correction of inventorship filed on 2-13-2003 is acknowledged.

#### ***Election/Restrictions***

The previous Office action (Paper No. 17) clearly indicates the search was done to the full scope of the invention (see the last paragraph of page 13 of the Office action) and the entire claims were examined to full scope of the claims, not just claims drawn to the elected species.

#### ***Information Disclosure Statement***

The signed copy of the information disclosure statement filed 2-14-2001 (Paper No. 5) is attached with this Office action.

#### ***Inventorship***

The request for the deletion of an inventor in this nonprovisional application under 37 CFR 1.48(b) will be processed.

#### ***Specification***

The specification remains objected because it is not clear EphrinA1-Fc used in the instant specification, which is incorporated by the reference to a publication (Miao et al, see page 3 line 3 of the specification) is the material consists of the same material commercially available. The record of the Office indicates that the supplemental information has not been received. The specification does not teach that EphrinA1-Fc used in the instant specification was obtained from the commercial vendor.

#### ***Claim Rejections - 35 USC § 112***

Rejection of claims 58-102 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because the amended claims no longer recite the unclear limitations.

Claims 58-102 **remain rejected** for reason of under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, **had possession** of the claimed invention.

Applicant amended the claims to method using "a compound" or "anti-EphA2 antibody" that "increases the phosphotyrosine content of EphA2" and then argues that the compounds that have such function could be screened easily and antibodies with such function could be made and screened. This argument is not convincing because it is apparent that applicant, at the time of the instant application was filed, had possession of only one such compound, EphrinA1-Fc, only one antibody such antibody, B2D6 that increases the phosphotyrosine content of EphA2. Based on only one such compound and only one such antibody, one cannot predict the types of additional compound and additional antibody that might increase the phosphotyrosine contents of EphA2 receptor. Since the genus includes a large number of unpredictable species, possession of one compound and one antibody is not seen as sufficient to reasonably convey possession of the entire genus.

Claims 58-102 **remain rejected** for the reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to **enable** one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant argues the in vitro experiments conducted in the specification is superior than other in vitro experiment and applicant now has in vivo data. The Office stated clearly in the previous Office action (see pages 6-12) that in vitro data is not enough for cancer treatment because the art recognizes cancer treatment is unpredictable. Applicant is invited to submit the additional vivo data to obviate this rejection.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

If Applicant could overcome the above 112, first paragraph rejections, claims 58-102 **remain rejected** for reason of record under 35 U.S.C. 112, first paragraph,

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because the specification, while being enabling for **B2D6** for decreasing the growth of metastatic breast cancer cells in culture and **EphrinA1-Fc** reduces colony formation of the EphA2 transformed MCF cells in soft agar, does not reasonably provide enablement for any other compounds for accomplishing the purpose stated in the preambles of claims 58-102. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant did not argue about this rejection and applicant did not overcome the rejection of record under enablement.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

May 18, 2003

  
ANTHONY G. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000